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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/075,970

02/14/2002

Michael Helmus

01-202

9278

27774 7590 01/10/2007
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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/075,970	Applicant(s) HELMUS, MICHAEL	
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7 and 9-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 and 9-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 6, 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Datta et al. (6,338,739) in view of Litner (6,589,286). Datta et al. disclose a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. Datta et al. fails to disclose the material of an inner core being ceramic or biodegradable metallic. Litner discloses a stent being made biodegradable ceramic, metal oxides for providing the necessary physical properties (col. 5, lines 15-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the material of inner core of Datta et al. with a ceramic or metallic materials as claimed in view of Litner. Doing so would amount to

mere substitution of one material for other within the same art that would allow to provide a desire physical properties for the stent of Datta et al.

Furthermore, it is well known in the art that the metallic or ceramic material would provide mechanical properties such as hardness and rigidity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute biodegradable polymeric inner core of Datta et al. with a biodegradable metallic or ceramic inner core in order to enhance the strength of the stent of Datta et al.

4. Claims 1, 3, 6, 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Datta et al. (6,338,739) in view of Steinke et al. (6,623,521). Datta et al. disclose a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time and wherein the inner core being made from polymer. Datta et al. fail to disclose the material of an inner core being ceramic or biodegradable metallic. Steinke et al. disclose the a stent being made from at least two layers and the backbone structure of the stent being made from biodegradable materials wherein the biodegradable materials being polymer or ceramic or biodegradable metallic (col. 17, lines 1-19). Steinke et al. also disclose that increasing the hardness of material for making a stent would allow for thinner stent thickness. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace biodegradable polymer inner core with ceramic or biodegradable metallic inner core for Datta et al.'s stent in order to enhance the strength as well as reduce the thickness of Datta's stent.

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5. Claims 1, 3, 6, 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO98/56312) in view of Steinke et al. (6,623,521). Wang et al. disclose a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. Although, Wang et al.'s stent is made from polymeric material, Steinke et al. disclose the a stent being made from at least two layers and the backbone structure of the stent being made from biodegradable materials wherein the biodegradable materials being polymer or ceramic or biodegradable metallic (col. 17, lines 1-19). Steinke et al. also disclose that increasing the hardness of material for making a stent would allow for thinner stent thickness. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace biodegradable polymer inner core with ceramic or biodegradable metallic inner core for Wang et al.'s stent in order to enhance the strength as well as reduce the thickness of Wang's stent.

6. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO98/56312) in view of Steinke et al. (6,623,521) further in view of Langer et al. (6,160,084). The teaching of Wang et al. in view of Steinke et al. discloses a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time wherein the outer cover being a biodegradable polymer and the inner core being

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ceramic, biodegradable metallic. The teaching of Wang et al. in view of Steinke et al. fails to disclose the outer cover being a shape memory biodegradable polymer. Langer et al. disclose biodegradable polymer being a shape memory polymer for making medical implant, stent etc. in order to provide the stent with memory shape and the biodegradable shape memory polymer comprising hydrophobic SMP coating for control degradation rate (col. 12, lines 59-67) and wherein the polymer compositions can combined with fillers reinforcement materials such as calcium-sodium-metaphosphate. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the cover material being shape memory biodegradable polymer and comprising hydrophobic coating in order to provide a memory shape for the stent of Wang et al. in view of Steinke et al. as well as to control degradation rate of the stent.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

January 5, 2007